

REMARKS/ARGUMENTS

Reconsideration and allowance of the above-referenced application are respectfully requested.

Applicants' attorney appreciates the Examiner's notification of the withdrawal of the Section 112, second paragraph and two Section 112, first paragraph rejections.

Further, Applicants' attorney sincerely appreciates the Examiner's indication of the allowability of claims 13-15.

Rejection of Claims 1-6, 10, 12-16, 59-80, 96 and 97 Under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 1-6, 10, 12-16, 59-80, 96 and 97 under Section 112, second paragraph as failing to comply with the written description requirement. In particular, the Examiner alleges that: 1) the mutants forms of HBsAg are not described and therefore the claimed monoclonal antibodies are not sufficiently described and 2) there are no specific structural limitations to the mutant forms of HBsAg.

In response, Applicants submit that the Examiner's concerns, giving rise to the rejection, have been adequately addressed by the amendments noted above. Thus, it is submitted that the rejection has been overcome and should be withdrawn accordingly.

Rejection of Claims 1-6, 12, 59-75 and 96 Under 35 U.S.C. 102(b)

The Examiner has rejected claims 1-6, 12, 59-75 and 96 under Section 102(b) as being anticipated by Mangold et al. In particular, the Examiner contends that since monoclonal antibodies H53 and H166 meet the structural and functional limitations of claims 1-6, 12, 59-75 and 96, the present claims are anticipated by Mangold et al.

In response, Applicants respectfully traverse the rejection. The Examiner will note that the priority date to which the present application is entitled is April

25, 1996. However, Mangold et al. was not accepted for publication until June 7, 1995 and was therefore not published until after the acceptance date.

Consequently, the Mangold et al. was not published more than one year before the priority date of the present application and thus cannot be used for purposes of a Section 102(b) rejection. The rejection is therefore moot and should be withdrawn accordingly.

Rejection of Claims 1-6, 12, 59-75 and 96 Under 35 U.S.C. 102(b) or Under 35 U.S.C. 103

The Examiner has rejected claims 1-6, 12, 59-75 and 96 under Section 102(b) as anticipated by, or in the alternative, under Section 103 as obvious over Waters et al. (WO 94/21812).

The Examiner alleges that Walters et al. disclose monoclonal antibodies SMH HBs 145/G/R/I and SMH HBs 145/G/R/II that bind to HBV variants containing a glycine to arginine substitution mutation at position 145 within the "a" determinant region of HBsAg. Further, the Examiner contends that Waters et al. also teach that these monoclonal antibodies can bind to both variant and wildtype HBsAg. Thus, the Examiner concludes that since there are no structural limitations to "mutant forms of HBsAg" in the present claims and since the Waters et al. antibodies can cross-react with both variant and wildtype HBsAg, the monoclonal antibodies of Waters et al. must inherently react with other "mutant forms of HBsAg" which contain epitopes that are structurally close to the epitopes to which the Waters et al. epitopes binds. Thus, the Examiner alleges that the monoclonal antibodies of Waters et al. meet the limitations of the claims directed to nucleic acids.

In response, Applicants submit that the claims, as amended above, adequately address the Examiner's concerns giving rise to the rejection. In particular, the pending claims do not include a recitation to the position 145 substitution mutation. Thus, the present claims are neither anticipated nor rendered obvious over Waters et al. The Section 102(b)/Section 103 rejection should be withdrawn accordingly.

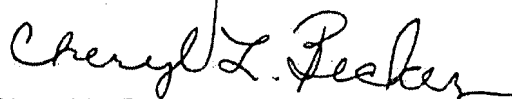
In conclusion, it is believed that the subject application is in condition of allowance and Notice to that effect is respectfully requested.

The Commissioner is hereby authorized to charge any additional Filing Fees required under 37 CFR §1.16, as well as any patent application processing fees under 37 CFR §1.17 associated with this communication for which full payment had not been tendered, to Deposit Account No. 01-0025.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below. If the Examiner notes any matters she believes may be expedited by a telephone interview, the Examiner is respectfully requested to contact the undersigned.

Respectfully submitted,

Richard Seton Tedder *et al.*

A handwritten signature in black ink, appearing to read "Cheryl L. Becker". The signature is fluid and cursive, with the first name "Cheryl" and last name "Becker" clearly distinguishable.

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